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10/756,101

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Steven M. Dubinett

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09/25/2006

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/756,101 | DUBINETT ET AL. | |
| | Examiner | Art Unit | |
| | Susan Ungar | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Claims 1-32 are pending in the application and are currently under prosecution.
 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 3. Claim 1 link inventions 1-12. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP, 804.01.
- Group 1. Claims 1-5 are drawn to an in vitro method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to SLC polypeptide as contemplated in the specification, classified in class 435, subclass 4.
- Group 2. Claims 1-5, 9 are drawn to an in vitro method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to SLC polypeptide as

contemplated in the specification and to a small molecule, classified in class 435, subclass 4.

Group 3. Claims 1-5, 9 are drawn to an in vitro method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to SLC polypeptide as contemplated in the specification and to a polypeptide agent, classified in class 435, subclass 4.

Group 4. Claims 1-5, 8 are drawn to an in vitro method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to a mammalian cell transduced with an expression vector encoding a SLC polypeptide as contemplated in the specification, classified in class 435, subclasses 4, 6.

Group 5. Claims 1-5, 8-9 are drawn to an in vitro method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to a mammalian cell transduced with an expression vector encoding a SLC polypeptide as contemplated in the specification and to a small molecule, classified in class 435, subclasses 4, 6.

Group 6. Claims 1-5, 8-9 are drawn to an in vitro method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to a mammalian cell transduced with an expression vector encoding a SLC polypeptide as contemplated in the specification and to a polypeptide agent, classified in class 435, subclasses 4, 6.

Group 7. Claims 1-7 are drawn to an in vivo method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to SLC polypeptide, classified in class 514, subclass 2+.

Group 8. Claims 1-7, 9 are drawn to an in vivo method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to SLC and to a small molecule, classified in class 514, subclass 2+.

Group 9. Claims 1-7, 9 are drawn to an in vivo method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to SLC polypeptide and to a polypeptide agent, classified in class 514, subclass 2+.

Group 10. Claims 1-8 are drawn to an in vivo method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to a mammalian cell transduced with an expression vector encoding a SLC polypeptide, classified in class 514, subclass 2+.

Group 11. Claims 1-9 are drawn to an in vivo method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to a mammalian cell transduced with an expression vector encoding a SLC polypeptide as contemplated in the specification and to a small molecule, classified in class 514, subclass 2+.

Group 12. Claims 1-9 are drawn to an in vivo method of inhibiting the growth of tumor cells comprising effecting an increase in the expression of IFN-Gamma and a decrease in TGF-Beta comprising exposing cells to a mammalian cell transduced

with an expression vector encoding a SLC polypeptide as contemplated in the specification and to a polypeptide agent, classified in class 514, subclass 2+.

4. Claims 10 and 20 link inventions 13-14. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 10 and 20. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP, 804.01.

It is noted that, given that the claims are drawn to inhibiting growth of spontaneous cancer cells, it will be assumed for examination purposes that both Groups 13 and 14 are drawn to in vivo methods of treatment.

Group 13. Claims 10-14, 20-25 are drawn to a method of inhibiting the growth of spontaneous cancer cells comprising exposing cells to SLC polypeptide, classified in class 514, subclass 2+. It is noted that, should Applicant elect the species of "cancer cells" for Group 7 above, the instant Group and Group 7 as it is drawn to the invention of Group 13 will be rejoined.

Group 14. Claims 10, 15-20, 26-31 are drawn to a method of inhibiting the growth of spontaneous cancer cells comprising exposing cells to a mammalian cell

transduced with an expression vector encoding a SLC polypeptide, classified in class 514, subclass 2+. It is noted that, should Applicant elect the species of “cancer cells” for Group 10 above, the instant Group and Group 10, as it is drawn to the invention of Group 14 will be rejoined.

Group 15. Claim 32 is drawn to a method of attracting a T lymphocyte to a site of a syngeneic tumor in a mammal classified in Class 514, subclass 2+.

Group 16. Claim 32 is drawn to a method of attracting a T lymphocyte to a site of a syngeneic tumor in a mammal classified in Class 514, subclass 2+.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-16 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In particular, they are drawn to both in vivo and in vitro methods, methods which are drawn to the treatment of both benign and malignant tumors, methods drawn to treatment of cancers with polypeptides and cells transfected with vectors as well as treatment with vectors encoding polypeptides. Further, the inventions are drawn not only to treatment of tumors, but also to the modulation of numerous molecules, apparently cytokines. Given the broadly diverse subject matter claimed, given the differences in objectives, method steps, response variables and criteria for success,

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Group 1-12 are further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising a materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success methods , wherein the methods are (a) inhibiting the growth of non-malignant tumor cells as encompassed by the claims (b) inhibiting the growth

8. Group 1-12 are further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the use of SLC to modulate the expression of various molecular substances with different structures and functions, wherein the species are (a) increase expression of IFN-gamma and decrease in expression of TGF-beta, (b) increase in expression of IFN-gamma and decrease in expression of TGF-beta and increase expression of GM-CSF, (c) increase in expression of IFN-gamma and decrease in expression of TGF-beta and increase expression of IL-12, (d) increase in expression of IFN-gamma and decrease in expression of TGF-beta and increase expression of Protein 10 polypeptide, (e) increase in expression of IFN-gamma and decrease in expression of TGF-beta and decrease expression of PGE2, (f) increase in expression of IFN-gamma and decrease in expression of TGF-beta and decrease expression of VEGF.

9. Groups 7-13 are further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the methods of administering SLC which are materially distinct methods which differ at least in method steps, and/or dosages and/or schedules used, response variables, wherein the methods are (a) intratumoral injection, (b) intra-lymph node injections.

10. Groups 1-16 are further subject to election of a single disclosed species. Claim 1 is generic to a plurality of disclosed patentably distinct species comprising SLC with different structures and modes of function, wherein the SLC is (a) human SLC, SEQ ID NO:1, (b) non-human SLC or SLC other than SEQ ID NO:1 as contemplated by the specification.

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.


Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.


Susan Ungar, PhD
Primary Patent Examiner
9/15/06